

### **REMARKS/ARGUMENTS**

Applicant has carefully reviewed and considered the Office Action mailed on June 23, 2009, and the references cited therewith.

Claims 54-55, 57-58, 60-62, and 64-65 are amended, claims 1-53, 59 and 63 are canceled, and claim 66 is added; as a result, claims 54-58, 60-62, and 64-66 are now pending in this application.

Applicant respectfully submits that claim 66 does not introduce any new subject matter and is intended to cover additional claimable subject matter fully supported by the originally filed specification.

#### **Examiner's Interview Summary**

Applicant and Examiner Bui conducted a telephone interview on August 19, 2009, to discuss claim language and proposed amendments thereof. Applicant and Examiner appeared to reach agreement that the proposed claim amendments are sufficient to overcome the 102(e) rejection based upon the Fogerty reference, although the Examiner may search for further references. Applicant thanks the Examiner for his time and consideration.

#### **§ 102 Rejection of the Claims**

Claims 54-62 and 64-65 were rejected under 35 USC §102(e) as being allegedly anticipated by or, in the alternative, under 35 U.S.C. §103(a) as obvious over Fogerty (EP Publication No. 0 686 379 A2). Applicant respectfully traverses the rejection as follows.

Applicant does not admit that the Fogerty reference is indeed prior art and reserves the right to sweat behind at a future date. Nonetheless, in the interest of advancing prosecution thereof, Applicant respectfully submits that the claims recited in the present application are patentably distinguishable from the teachings of the Fogerty reference for at least the following reasons.

Applicant notes that the Fogerty reference appears to teach that “the graft structure 10 includes a fabric liner 12 and a radially compressible perforate tubular frame 14.” (Col. 10, lines 14-16). The Fogerty reference appears to also teach, “The liner 12 will usually pass outward from the inner lumen of the tubular frame 14 to the exterior of the frame through the gap between adjacent band members, as illustrated in Fig. 1.” (Col. 10, lines 48-52). Additionally, referring to Fig. 5, the Fogerty reference appears to teach, “The fabric 24 defines a common flow lumen at its upper end and a pair of divergent flow lumens at its lower end, one in each leg 26 and 28. The legs 26 and 28 are preferably not covered by the frame of the anchor 22.” (Col. 13, lines 3-8).

Hence, Applicant respectfully submits that the Fogerty reference does not teach a proximal prosthesis having at least two transversely placed tapering portions that extend from an intermediate portion to the distal end of the proximal prosthesis to form a bifurcated prosthesis, the proximal prosthesis also having at least one distal orifice at the distal end of at least one of the tapering portions which when expanded serves to receive the proximal end of the at least one distal prosthesis, where the proximal prosthesis and the at least one distal prosthesis each comprises an expandable stent constructed with a wire skeleton having one or more parts that extends from the respective proximal ends to the respective distal ends.

In contrast, Applicant’s independent claim 54, as currently amended, presently recites in part:

the proximal prosthesis having at least two transversely placed tapering portions that extend from an intermediate portion to the distal end of the proximal prosthesis to form a bifurcated prosthesis;

the proximal prosthesis also having at least one distal orifice at the distal end of at least one of the tapering portions which when expanded serves to receive the proximal end of the at least one distal prosthesis;

wherein the proximal prosthesis and the at least one distal prosthesis each comprises an expandable stent constructed with a wire skeleton having one or more parts that extends from the respective proximal ends to the respective distal ends;

That is, the Fogerty reference appears to teach a fabric that defines a pair of divergent flow lumens at its lower end, one in each leg and that the legs are not covered by the frame. Applicant respectfully submits that the fabric of Fogerty may be used to construct an equivalent of the distal end having distal orifices of the present disclosure, although Applicant does not admit same. However, the Fogerty reference does not teach an expandable stent constructed with a wire skeleton having one or more parts that extends from the respective proximal ends to the respective distal ends, which includes having at least two transversely placed tapering portions that form a bifurcated prosthesis with at least one distal orifice at the distal end of at least one of the tapering portions which when expanded serves to receive a proximal end of the at least one distal prosthesis. Applicant also respectfully submits that a fabric, as taught by the Fogerty reference, is not expandable and does not exist in an expanded state in the manner of the expandable stent described in the specification and recited in the claims of the present application.

The last element of Applicant's independent claim 54 recites:

wherein a cross-sectional area of the at least one distal orifice when expanded is sufficiently less than that of the proximal end of the at least one distal prosthesis when expanded within the at least one distal orifice so as to form a seal between the proximal and distal prostheses.

The Office Action states, referring to Figs. 8-11 of Fogerty, that the inside distal prosthesis must inherently be bigger than the outside proximal prosthesis to have a tight fitting seal between the inside distal prosthesis and the outside proximal prosthesis. However, Applicant respectfully submits that the Fogerty reference does not teach such and the fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. That is, to establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference and that it would be so recognized by persons of ordinary skill. The

mere fact that a certain thing may result from a given set of circumstances is not sufficient.

Applicant respectfully submits that a fabric, as apparently taught by the Fogerty reference to form the equivalent of the one or more distal orifices, is not expandable and does not exist in an expanded state in the manner of the expandable stent described in the specification and recited in the claims of the present application. Hence, Applicant respectfully submits that it is not inherent in the Fogerty reference that a cross-sectional area of the at least one distal orifice **when expanded** is sufficiently less than that of the proximal end of the at least one distal prosthesis **when expanded** within the at least one distal orifice so as to form a seal between the proximal and distal prostheses.

Moreover, the Office action appears to take Official Notice that it would have been “obvious to one of ordinary skill in the art” to provide a tight fitting seal between the inside distal prosthesis and the outside proximal prosthesis by the inside distal prosthesis being bigger than the outside proximal prosthesis. Applicant respectfully traverses this attempted use of Official Notice as being improper in that one or more of the following necessary elements of a prima facie case is absent.

Applicant respectfully submits that the Office Action attempts to officially notice legal conclusions, namely, that various elements were “obvious to one of ordinary skill in the art”. Official Notice, however, is only proper for facts that are of a “notorious character” and that are “capable of instant and unquestionable demonstration”, per MPEP 2144.03(A). It is improper to use Official Notice for conclusions of law. Courts have long rejected the notion that Official Notice can be taken on the state of the art. Hence, the attempt by the Office Action to officially notice the level of ordinary skill in the art at the time of the invention is improper as a matter of law. Applicant notes that an Office Action is expressly required to provide specific factual findings predicated on sound technical and scientific reasoning to support taking Official Notice, per MPEP 2144.03(B). The Office Action should present the explicit basis upon which the Official Notice is based so that the Applicant is able to challenge the assertion, also per MPEP 2144.03(B).

Further, the Supreme Court has long held that “obviousness is a question of law based on underlying fact inquiries, including . . . ascertaining the differences between the claimed invention and the prior art.” See *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966). Applicant notes that the instructions of MPEP section 2143 – Examples of Basic Requirements of a *Prima Facie* Case of Obviousness – support a conclusion that a determination of obviousness requires at least a suggestion of all the features of a claim, which is supported by the Supreme Court decision stating that “there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” See *KSR Int’l v. Teleflex Inc.*, 127 S.Ct. 1727, 1741 (2007).

Applicant respectfully submits that a fabric, as apparently taught by the Fogerty reference to form the equivalent of the one or more distal orifices, is not expandable and does not exist in an expanded state in the manner of the expandable stent described in the specification and recited in the claims of the present application and that there is not “at least a suggestion” of such in the Fogerty reference. Hence, Applicant respectfully submits that it is not obvious to one of ordinary skill in the art that a cross-sectional area of the at least one distal orifice when expanded is sufficiently less than that of the proximal end of the at least one distal prosthesis when expanded within the at least one distal orifice so as to form a seal between the proximal and distal prostheses because there is no “articulated reasoning with some rational underpinning to support the legal conclusion of obviousness” based upon the Fogerty reference or otherwise.

Applicant notes that existing procedures for treating abdominal aortic aneurisms, for example, have a number of drawbacks and limitations, as described in the Background of the Invention, for example in paragraph 0008, of the specification of Applicant’s application. In contrast, the subsequent recitation of the specification of Applicant’s application, for example the Summary of the Invention in paragraphs 0009-0045, recites a number of advantages obtained through implementing the teachings thereof.

Applicant has presented the just-recited unmet needs that have been resolved as secondary considerations along with the improper applications of Official Notice. As such, Applicant respectfully submits that the Official Notice has been adequately traversed, per MPEP 2144.03(C). Accordingly, Applicant respectfully requests that the Official Notices be withdrawn. In the alternative, Applicant respectfully requests a “citation to some reference work recognized as a standard in the pertinent art”, one or more of which support stating that the recited elements of independent claim 54 would have been obvious to one of ordinary skill in the art, per MPEP 2144.03(A).

Applicant’s independent claim 57, as currently amended, presently recites in part:

the proximal prosthesis having at least two transversely placed tapering portions that extend from an intermediate portion to the distal end of the proximal prosthesis to form a bifurcated prosthesis;

the proximal prosthesis also having a distal orifice at the distal end of at least one of the tapering portions that when expanded receives at least one proximal end of the first and second distal prostheses;

wherein each of the proximal and distal prostheses comprises an expandable stent constructed with a wire skeleton having one or more parts that extends from the respective proximal ends to the respective distal ends;

In addition, Applicant’s independent claim 60, as currently amended, presently recites in part:

the proximal prosthesis having at least two transversely placed tapering portions that extend from an intermediate portion to the distal end of the proximal prosthesis to form a bifurcated prosthesis,  
the proximal prosthesis also having at least two distal orifices at the distal ends of the tapering portions which when expanded serve to receive the proximal ends of the pair of distal prostheses, wherein each of the proximal and distal prostheses comprises an expandable stent constructed with a wire skeleton having one or more parts that extends from the respective proximal ends to the respective distal ends

As such, Applicant respectfully submits that the Fogerty reference does not teach, suggest, or render obvious each and every element and limitation of Applicant's independent claims 54, 57, and 60, as currently amended. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the 102/103 rejection of independent claims 54, 57, and 60, as currently amended, as well as those claims that depend therefrom.

*§103 Rejection of the Claims*

Claim 62 was rejected under 35 USC § 103(a) as being allegedly unpatentable over Fogerty (EP Publication No. 0 686 379 A2) in view of Piplani, et al. (U.S. Patent No. 5,489,295). Applicant respectfully traverses the rejection as follows.

Claim 62 depends from independent claim 60. As presented above, Applicant respectfully submits that independent claim 60, as currently amended, is in condition for allowance in view of the Fogerty reference. Applicant respectfully submits that the Piplani reference does not cure the deficiencies of the Fogerty reference. That is, the Fogerty and Piplani references, individually or in combination, do not teach, suggest, or render obvious:

the proximal prosthesis having at least two transversely placed tapering portions that extend from an intermediate portion to the distal end of the proximal prosthesis to form a bifurcated prosthesis, the proximal prosthesis also having at least two distal orifices at the distal ends of the tapering portions which when expanded serve to receive the proximal ends of the pair of distal prostheses, wherein each of the proximal and distal prostheses comprises an expandable stent constructed with a wire skeleton having one or more parts that extends from the respective proximal ends to the respective distal ends

as recited in part by Applicant's independent claim 60, as currently amended.

Accordingly, Applicant respectfully request reconsideration and withdrawal of the 103 rejection of dependent claim 62.

**CONCLUSION**

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's below listed attorney at (612) 236-0126 to facilitate prosecution of this matter.

**CERTIFICATE UNDER 37 CFR §1.8:** The undersigned hereby certifies that this correspondence is being filed electronically with the U.S. Patent and Trademark Office on this 18 day of

February, 2010.

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